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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,860	09/12/2003	Gregory P. Pogue	LSBC-POGE-A1A	7908

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,860	POGUE ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *3 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-10* is/are rejected.

7)☒ Claim(s) *1, 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4 Aug 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner acknowledges the election, without traverse, of Group III (claims 1-2, 5-10) directed to gene silencing vectors and method of using said vector, in the reply filed on 30 June 2006.

Claim Status

Claims 1-10 are pending. Claims 3-4 are withdrawn by applicant. Claims 1-2 and 5-10 are under current examination.

Formality Compliance

Although they are withdrawn, applicant should note that the amendments to the claims 3-4 do not comply with the Revised Amendment Practice of 37 CFR 1.121 (See OG Notice 23 September 2003). Specifically, the text of withdrawn claims must be included in the listing of the claims and the text of canceled claims must be omitted. Withdrawn claims that are amended should be labeled with the status identifier "Withdrawn -- currently amended" according to 37 CFR 1.121(c)(2). Correction is required in the response to this Office Action.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 4 August 2004 consisting of 3 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit from provisional U.S. Application No. 60/410,879, filed 13 September 2002. The instant application has been granted the benefit date, 13 September 2002, from the application 60/410,879.

Claim Objections

Claim 1 is objected to because of the following informalities: The colon punctuation after "with" does not have any purpose. There is a missing word (perhaps "a") in the following phrase, "is followed by different sequence".

Claim 9 is objected to because of the following informalities: There is a missing word (perhaps "a") in the following phrase, "delivery of hairpin RNA".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains numerous clarity issues. A DNA cannot contain a virus. The origin of the hairpin sequence claimed is not clear; it is from the RNA virus, the host, or synthetic? There is no antecedent basis for the phrase "the first". It is not clear to which sequences the phrase "no intervening sequence" refers. For examination purposes, the examiner is interpreting the meaning of claim 1 to be an RNA virus comprising a sequence of greater than 20bp that contains a hairpin sequence consisting of an inverted repeat.

Claim 2 is objected to as being indefinite, because the claim appears to be claiming "cytoplasmic inhibition." This is neither a product nor a method. If it is a method, claim does not set forth any steps involved in the method/process. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable

degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6. For the purposes of examination, the examiner is interpreting this claim to mean a method of gene silencing that induces cytoplasmic inhibition of gene expression through the action of a DNA construct of claim 1.

Claim 5 is objected to because it is unclear what the positive method step is for determination of nuclear gene function.

Claim 8 is objected to because "very short" and "highly active" are indefinite terms. The specification fails to define the terms. It is unclear what sequence length is encompassed by "very short" and what level of activity is encompassed by "highly active", and thus, the metes and bounds of the claims are unclear. Clarification of these terms is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement;* (Federal Register/Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claim 1 is broadly drawn, such that it applies to any RNA virus containing hairpin sequences corresponding to sequences in any target cell. The invention claims a genus of viruses that comprise a large genus of hairpin structures that can silence genes in virtually any organism. However, the working examples provided in the instant application only utilize Tobacco Mosaic Virus (TMV) and Barley Stripe Mosaic Virus (BSMV), and only silence Green Fluorescent Protein (GFP) and Phytoene Desaturase (PDS) target genes, in only barley and *Nicotiana benthamiana* target organisms. Only PDS is a naturally occurring gene that could be said to demonstrate that the invention has support for silencing naturally occurring endogenous genes. While there is description for hairpin sequences useful for silencing GFP in barley and *N. benthamiana,* this example does not demonstrate that any endogenous gene can be silenced in any plant. Beyond the two species of plant genes cited in the instant

application, there is little support for the application of this invention in all other plant species. Clearly there is support for sequence compositions useful in gene silencing of the two examples of target genes (GFP and PDS) in barley and *Nicotiana benthamiana* using TMV and BSMV. Beyond these sequences, the instant application does not support the broadly claimed hairpin sequences needed for making the construct of claim 1. More importantly, the specification does not provide a practical example of gene silencing in any animal cell (or specifically mammalian cell), using alphavirus or rubivirus.

The Revised Interim Guideline for Examination of Patent Applications under 35 USC § 112, p1 "Written Description" Requirement (Federal Register/ Vol 66. No 4, Friday January 5, 2001) states "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (column 2, page 71436, emphasis added).

Appellants are reminded adequate written description requires more than a mere statement that it is a part of the invention and reference to a potential method of isolating or using it. *See Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed Cir. 1991). In

the instant case, the specification fails to describe the structure of the hairpin sequences capable of silencing any given gene, or fails to particularly point out, particularly pointing out critical consensus regions or motifs of the genus. What are the particular sequences that can silence specific genes? Are there particular regions of the target genes that are most susceptible to the action of the hairpin? Thus it fails to provide adequate written description for the claimed genus.

Vas-Cath Inc. v. Mabhurkar, 19USPQ2d 1111, clearly states that "APPLICANT MUST CONVEY WITH REASONABLE CLARITY TO THOSE SKILLED IN THE ART THAT, AS OF THE FILING DATE SOUGHT, HE OR SHE WAS IN POSSESSION OF THE INVENTION. THE INVENTION IS, FOR PURPOSES OF THE 'WRITTEN DESCRIPTION' INQUIRY, *WHATEVER IS NOW CLAIMED*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize the [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed genus other than hairpin silencing sequences in plants.

Claims 2 and 5-10 are also rejected because they depend from claim 1, and thus contain the above issues due to said dependence.

Claims 1-2 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for gene silencing of GFP and PDS in barley and *Nicotiana benthamiana* using TMV and BSMV, does not reasonably provide enablement for gene silencing of every target gene in any species of plant or animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some 'experimentation.'" Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

The breadth of the claims encompasses a genus of viruses that comprise a large genus of hairpin structures that can silence genes in virtually any organism. As discussed supra, the specification fails to describe the genus of hairpin sequences and would require undue experimentation to discover these sequences. The specification only discloses and provides guidance for RNA hairpin mediated gene silencing of two example target genes (GFP and PDS) in barley and *Nicotiana benthamiana* using TMV and BSMV.

Claim 2 encompasses gene silencing in a mammal, which is a complex organism. The specification does not provide guidance for or a working example for gene silencing in a whole mammal or in mammalian cells using alphavirus or rubivirus.

The absence of working examples directed to gene silencing of target sequences in mammalian cells necessitates further experimentation. Additionally, no working examples were provided that utilize alphavirus, rubivirus or any animal or mammalian virus. Therefore, the specification does not provide sufficient guidance on how to make and use RNA vectors capable of silencing genes in mammalian cells. In fact, the state of the art teaches that gene silencing in adult mammalian cells by dsRNA is not a highly successful technique (Vance et al. Science. vol 292. 22 June 2001. p. 2280). Furthermore, Ui-Tei et al. (FEBS Letters 479 (2000) 79-82) teach "In contrast to invertebrates, only limited success with RNAi has been noted in mammals " (page 81, section 3.2). Ui-Tei et al. also teach "dsRNA required for RNAi in CHO-K1 cells was about 2500 times that for RNAi in Drosophila S2 cells," (p. 82), indicating that

there is some different mechanism involved in mammalian cells that makes gene silencing more difficult than that of lower animals and plants. Consequently, there is ample reason to conclude that there would be a high degree of unpredictability in a mammalian embodiment of the instant invention.

In conclusion, given the breadth of the claims and the limited scope of the specification, an undue quantity of experimentation is require to make and use the invention beyond the scope of gene silencing of GFP and PDS in barley and *Nicotiana benthamiana* using TMV and BSMV.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Symonds et al. (US-5,712,384).

Claim 1 is directed to Claims 1 is directed to "infectious clone of an RNA virus...hairpin sequence...gene encoded within the nucleus of the target host...hairpin sequence...greater than 20bp in length."

Symonds et al teach an "Transfer vectors comprising RNA...containing a nucleotide sequence...which gives rise to..."(column 11, lines 26-28) a "hairpin" (abstract). The specific target of the Symonds invention is HIV, which has been

integrated into the host genome. Therefore the target gene is encoded within the nucleus of the host. Symonds et al teach a hairpin size of "65bp." (column 17, line 42).

Accordingly, Symonds et al. anticipated the instant claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham (US-6,573,099 B2) in view of Scholthof et al. (Annual Review of Phytopathology, September 1996, Vol. 34, Pages 299-323)

Claims 1 is directed to "DNA construct...infectious clone of an RNA virus...hairpin sequence...gene encoded within the nucleus of the target host...hairpin sequence...greater than 20bp in length...sense...reverse complement orientation...no intervening sequence."

Graham teaches "two identical... genes...in a head-to-head configuration as an inverted repeat or palindrome" (column 11, lines 12-16) "about 20-30 nucleotides in length" (column 6, line 37) where the "target gene...is endogenous to cell, tissue, or organ" (column 5, lines 1-2). Furthermore, Graham teaches that the "synthetic genes...may be introduced into a suitable cell...as...virus particle...virus vector." (column 13, lines 57-66).

Claim 2 is directed to "cytoplasmic inhibition of...gene expression." Graham teaches "modifying gene expression in a cell...capable of repressing, delaying, or otherwise reducing expression" (column 1, lines 9-13).

Claim 5 is directed to a "method for determining nuclear function." Graham "sought to elucidate the mechanisms of downregulation of gene expression...to provide improved methods therefor" (column 1, lines 50-12) and taught "gene encodes a function which is essential...DNA polymerase or RNA polymerase" (column 4, lines 47-49).

Claim 8 is directed to "vector exhibits improved genetic stability." Graham teaches, "inherent instability of palindromic...long...inverted repeated nucleotide sequences....Notwithstanding, such difficulties...following standard procedures such as...the invention...reducing...to a level which eliminates or minimizes recombination events." (column 10, lines 27-40). The lack of recombination implies genetic stability.

While Graham does not specifically teach using an RNA virus for hairpin expression, as described above, he teaches the use of a generic virus particle as a vector for the hairpin. Graham does not teach the specific RNA viruses tobacco mosaic virus, barley striped mosaic virus, alphavirus and rubivirus.

Claims 6-7 are directed to tobacco mosaic virus (TMV) and barley striped mosaic virus. Scholthof et al teach tobacco mosaic virus (TMV) and barley striped mosaic virus (BSMV) as plant virus gene vectors for transient expression in plants. (p. 299, introduction, p.307).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of Graham and Scholthof et al. to generate specific RNA viruses (viruses tobacco mosaic virus, barley striped mosaic virus) as vectors for hairpin gene silencing sequences. Utilizing TMV and BSMV as vectors for in the invention of Graham as applied to plants, would have been obvious because these viruses are commonly used as expression vectors for plants. Furthermore, an art understood method of delivering gene therapy products is to choose viruses specific to certain hosts.

The person of ordinary skill in the art would have been motivated to combine Scholtof viruses with the Graham invention because "plant virus gene vectors for expression of foreign genes in plants provides attractive biotechnological tools" (Scholtof et al. p.299 abstract).

The skilled artisan would have had a reasonable expectation of success in combining the teachings of Graham and Scholthof et al. because Graham teaches his invention for a "plant" (Graham, abstract) and Scholthof et al teach the appropriate plant virus vectors. All of the technologies were well developed enough at the time of the instant application to assure success.

Therefore the method as taught Graham in view of Scholthof et al. would have been *prima facie* obvious over the method of the instant application.

Claims 1, 2, 5, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham (US-6,573,099 B2) in view of Kovacs et al. (US-7,034,141).

The teachings of Graham are described above.

Claim 9 is directed to the vector infecting "mammalian cells." Graham teaches the invention "in an animal cell" (column 25, line 64). Graham teaches "promoter sequence operable in said cell." (column 26, line 64). Further, Graham teaches the "promoter controlling expression...will usually be selected to confer expression in the cell, tissue or organ over the entire life cycle of the virus when the viral target genes are expressed at different stages of infection." (column 10, lines 65 through column 11, line

2). Graham also teaches "HIV-1" (column 6, line 31). Therefore any animal that could be infected with HIV-1 would be a mammal.

Claim 10 is directed to "alphavirus, rubivirus virus families." Kovacs et al. teach "alphaviruses...are positive-strand RNA viruses...are especially attractive viral expression vectors" (column 1, line 21-26) and "rubiviruses... can be substituted" (column 2, lines 12 & 28-29).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of Graham, and Kovacs et al. to generate specific RNA viruses (alphavirus and rubivirus) as vectors for hairpin gene silencing sequences. Utilizing alphavirus and rubivirus as vectors for in the invention of Graham as applied to animals, would have been obvious because these viruses were well known as expression vectors. . Furthermore, an art understood method of delivering gene therapy products is to choose viruses specific to certain hosts.

The person of ordinary skill in the art would have been motivated to combine Kovacs viruses with the Graham invention because alphaviruses and rubiviruses have been successfully used as expression vectors. Furthermore, as quoted above, they "are especially attractive viral expression vectors" (column 1, line 26).

The skilled artisan would have had a reasonable expectation of success in combining the teachings of Graham and Kovacs et al. because Graham teaches his invention for a "animal or plant" (Graham, abstract) and while Kovacs et al teach the appropriate animal virus vectors, alphavirus and rubivirus.

Therefore the method as taught Graham in view of Kovacs et al. would have been *prima facie* obvious over the method of the instant application.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave Nguyen** can be reached on **571-272-0731**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
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PRIMARY EXAMINER